Application No.: NEW APPLICATION

Docket No.: KZI-001US 10/540228 JC17 Rec'd PCT/PTO 21 JUN 2005

## In the Claims:

Please cancel claims 1-72.

Please add new claims 73-102.

## Claims 1-72. Cancelled.

- 73. (New) A method of treating infertility in a female mammal comprising administering a pharmaceutical agent comprising a gonadotrophin releasing hormone (GnRH) agonist which supports the luteal phase, wherein the GnRH agonist is administered either
  - i) after a spontaneous ovulation, or
  - ii) after stimulation of follicular growth and induction of final follicular maturation and ovulation.
- 74. (New) The method according to claim 73, wherein stimulation of follicular growth and induction of final follicular maturation and ovulation is effected by the administration of at least one additional agent.
- 75. (New) The method according to claim 74, wherein the additional agent triggering final follicular maturation and ovulation is a GnRH agonist.
- 76. (New) The method according to claim 75, wherein the additional agent triggering final follicular maturation and ovulation is the GnRH agonist administered to support the luteal phase.
- 77. (New) The method according to claim 75, wherein the additional agent triggering final follicular maturation and ovulation is a GnRH agonist different from the GnRH agonist administered to support the luteal phase.
- 78. (New) The method according to claim 73, wherein the GnRH agonist is selected from the group consisting of a natural (native) GnRH, a recombinant GnRH, a synthetic peptide agonist of GnRH, a non-peptide GnRH agonist, and a molecular chimera of GnRH.
- 79. (New) The method according to claim 78, wherein the synthetic peptide is selected from the group comprising buserelin(e), nafarelin(e), triptorelin(e), leuprorelin(e),

Application No.: NEW APPLICATION Docket No.: KZI-001US

goserelin(e), deslorelin(e) and histrelin(e), analogs thereof, and a combination of two or more of these agonists.

- 80. (New) The method according to claim 79, wherein the GnRH agonist is buserelin.
- 81. (New) The method according to claim 73, wherein the pharmaceutical agent which supports the luteal phase is administered after administration of a GnRH antagonist during the last days of follicular growth stimulation.
- 82. (New) The method according to claim 73, wherein the pharmaceutical agent which supports the luteal phase is administered in combination with another luteal support agent selected from the group consisting of natural progesterone, a progestagen, human chorionic gonadotropin (hCG), luteinizing hormone (LH), one or more isoforms of LH or of hCG, a peptidomimetic of LH or of hCG, an LH or an hCG analog with a modified pharmacokinetic, a phosphodiesterase inhibitor, a non-peptidic modulator of cyclicAMP, and a combination of two or more of these agents.
- 83. (New) The method according to claim 73, wherein the pharmaceutical agent which supports the luteal phase is administered in combination with a cytokine involved in embryo implantation mechanisms.
- 84. (New) The method according to claim 83, wherein the cytokine is selected from the group consisting of native Leukemia Inhibitory Factor (LIF), recombinant LIF, a peptidic or a non-peptidic agonist analog of LIF, and a combination thereof.
- 85. (New) The method according to claim 74, wherein the stimulation effected by the administration of the additional agent is followed, before ovulation, by an oocyte retrieval procedure, wherein at least one oocyte is obtained.
- 86. (New) The method according to claim 85, wherein the oocyte undergoes an *in vitro* maturation.
- 87. (New) The method according to claim 85, wherein the oocyte undergoes an *in* vitro fertilization.

Application No.: NEW APPLICATION Docket No.: KZI-001US

88. (New) The method according to claim 74, wherein the stimulation effected by the administration of the additional agent is followed, after ovulation trigger, with an intra-uterine insemination (IUI).

- 89. (New) The method according to claim 73, wherein the GnRH agonist route of administration is selected from the group consisting of intra-nasal, oral, sub-cutaneous, intra-muscular, vaginal, rectal, transdermal, and pulmonary.
- 90. (New) The method according to claim 74, wherein the additional agent stimulating follicular growth is selected from the group comprising human menopausal gonadotrophins (hMG), urine-derived follicle stimulating hormone (FSH), recombinant FSH, one or several FSH isoforms, FSH mimetics, FSH analogs with a modified phamacokinetic, selective estrogen receptors modulators (SERM), aromatases inhibitors, phosphodiesterase inhibitors, and a combination of two or more of these agents.
- 91. (New) The method according to claim 90, wherein the SERM is selected from the group consisting of clomiphen(e), tamoxifen(e), raloxifen(e), and a combination of two or more of these agents.
- 92. **(New)** The method according to claim 90, wherein the aromatase inhibitor is selected from the group consisting of anastrozole, letrozole, exemestane, and a combination of two or more of these agents.
- 93. (New) The method according to claim 74, wherein the additional agent triggering final follicular maturation and ovulation is selected from the group consisting of hCG, LH, one or more isoforms of hCG or LH, hCG and LH peptido-mimetics, hCG and LH analogs with a modified pharmacokinetic, phosphodiesterase inhibitors, and a combination of two or more of these agents.
- 94. **(New)** The method according to claim 90, wherein the phosphodiesterase inhibitor is theophyline.
- 95. (New) The method according to claim 73, wherein the female mammal is a woman.

Application No.: NEW APPLICATION Docket No.: KZI-001US

96. (New) The method according to claim 76, wherein the GnRH agonist is buserelin and is administered intra-nasally, at least once, at a dose of between 50 and 600  $\mu$ g.

- 97. (New) The method according to claim 96, wherein buserelin is administered intra-nasally at a dose of 200  $\mu$ g.
- 98. (New) A method of treating infertility in a female mammal comprising administering a pharmaceutical agent which comprises a GnRH agonist comprising buserelin, which supports luteal phase after stimulation of follicular growth and induction of final follicular maturation and ovulation with one or more additional agents, wherein said buserelin is administered intra-nasally within the first three days following ovulation trigger at a dose of between 50 and 400  $\mu$ g and at a frequency between three times a day and once every three days for a duration of 7 to 28 days.
- 99. (New) Method according to claim 98, wherein buserelin is administered on the first day following ovulation trigger.
- 100. (New) Method according to claim 98, wherein buserelin is administered at a dose of 100 µg.
- 101. **(New)** Method according to claim 98, wherein buserelin is administered for a duration of 14 days.
- 102. (New) A kit for the treatment of infertility in female mammals comprising
  a) a pharmaceutical agent comprising a GnRH agonist which supports luteal phase,
  formulated in a dosage and unit required for one cycle of treatment; and
  - b) at least one additional agents which triggers final follicular maturation and ovulation.